The opinion in support of the decision being entered today was **not** written for publication and is **not** precedent of the Board.

Paper No. 27

UNITED STATES PATENT AND TRADEMARK OFFICE

MAILED

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

SEP 2 6 2003

PAT. & T.M. OFFICE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JOSEPH P. STEINER and GREGORY S. HAMILTON

Application No. 09/825,896

ON BRIEF

Before WILLIAM SMITH, SCHEINER and PAWLIKOWSKI, <u>Administrative</u>

Patent Judges.

PAWLIKOWSKI, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 25, 26, and 27.

Claim 25 is representative of the subject matter on appeal and is set forth below:

25. A pharmaceutical composition comprising:
(i) an effective amount of a compound of formula I:

or a pharmaceutically acceptable salt or hydrate thereof, wherein

R is selected from the group consisting of a C_1-C_9 straight or branched chain alkyl or C_2-C_9 straight or branched chain alkenyl, C_3 or C_5 cycloalkyl, C_5-C_7 cycloalkenyl, and Ar_1 ,

wherein said alkyl or alkenyl is optionally substituted with $C_3\text{-}C_8$ cycloalkyl,

 C_1-C_4 alkyl, C_2-C_4 alkenyl, or hydroxy, wherein said cycloalkyl or cycloalkenyl is optionally substituted with C_1-C_4 alkyl, C_2-C_4 alkenyl, or hydroxy,

Ar₁ is selected from the group consisting of 1-naphthyl, 2-naphthyl, 2-indolyl, 3-indolyl, 2-furyl, 3-furyl, 2-thiazolyl, 3-thienyl, 2-pyridyl, 3-pyridyl, 4-pyridyl, and phenyl,

wherein said Ar_1 has one to three substituents which are independently selected from the group consisting of hydrogen, halo, hydroxyl, nitro, trifluoromethyl, C_1 - C_6 straight or branched alkyl or C_2 - C_6 straight or branched alkenyl, C_1 - C_4 alkoxy or C_2 - C_4 alkenyloxy, phenoxy, benzyloxy, and amino;

x is selected from the group consisting of oxygen, sulfur, methylene, and H_2 ;

Y is selected from the group consisting of oxygen and NR_2 , wherein R_2 is hydrogen or C_1 - C_8 alkyl; and

Z is selected from the group consisting of C_2 - C_6 straight or branched chain alkyl or C_2 - C_6 straight or branched chain alkenyl, and Ar_2 ,

wherein the C_2 - C_6 straight or branched alkyl is substituted in one or more positions with Ar_1 as defined above, C_3 - C_8 cycloalkyl, or cycloalkyl connected by a C_1 - C_6 alkyl or C_2 - C_6 alkenyl;

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> Ar₂ is selected from the group consisting of 2indolyl, 3-indolyl, 2-furyl, 3-furyl, 2-thiazolyl, 2thienyl, 3-thienyl, 2-pyridyl, 3-pyridyl, 4-pyridyl, and phenyl,

> wherein said Ar₂ has one to three substituents which are independently selected from the group consisting of hydrogen, halo, hydroxyl, nitro, trifluoromethyl, C₁-C₆ straight or branched alkyl or C_2 - C_6 straight or branched alkenyl, C_1 - C_4 alkoxy or C_2 -C₄ alkenyloxy, phenoxy, benzyloxy, and amino; or Z is a fragment having the following formula:

wherein

 R_3 is a C_1 - C_9 straight or branched alkyl or unsubstituted Ar₁, wherein said C_1-C_9 straight or branched alkyl is optionally substituted with C2-C8 cycloalkyl or Ar₁ as defined above;

 X_2 is O or NR_5 , where R_5 is selected from the group consisting of hydrogen, C₁-C₆ straight or branched alkyl, and C2-C6 straight or branched alkenyl; and

 R_4 is selected from the group consisting of phenyl, benzyl, C_1-C_5 straight or branched alkyl or C_2 -C₅ straight or branched alkenyl, and C₁-C₅ straight or branched alkyl or C_2 - C_5 straight or branched alkenyl substituted with phenyl;

(ii) a second hair revitalizing compound; and (iii) a pharmaceutically acceptable carrier.

The examiner relies upon the following reference as evidence of unpatentability:

Steiner et al. (Steiner) 6,239,164B1 May 29, 2001

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Claims 25-27 stand rejected under 35 U.S.C. § 101 as claiming the same invention as that of claims 22-24 of Steiner.

On page 3 of the Brief, appellants states that the claims stand or fall together according to the ground of rejection. We therefore consider claim 25. 37 CFR § 1.192(c)(7) and (8)(2001).

OPINION

We have carefully reviewed appellants' Brief and the examiner's Answer. This review has led us to conclude that the examiner's 35 U.S.C. § 101 rejection is well-founded for the reasons set forth below.

I. Claim Construction of the Claims of Steiner

Each of the claims 22, 23, and 24 of Steiner depend upon claim 21.

For illustrative purposes, if claim 22 was rewritten in independent form, including the limitations of base claim 21, claim 22 would read, in part, as set forth below. For the sake of simplicity, the text regarding formula I of claim 22 has been omitted, but is the same as that set forth in column 28, lines 30-68 through column 29, lines 1-25.

22. A pharmaceutical composition comprising:

(i) an effective amount of a nonimmunosuppressive pyrrolidine carboxylate or
pyrrolidine amide compound having an affinity for
FKBP-type immunophilins; [The pharmaceutical
composition of claim 21]

wherein said compound is of formula I:

or a pharmaceutically acceptable salt or hydrate thereof, wherein [text omitted here]

(iii) a second hair revitalizing compound; and (iii) a pharmaceutically acceptable carrier.

Likewise, claim 23 and claim 24 would include each of 3 components if rewritten in independent form, having the limitations of base claim 21.

In view of the above, we interpret claims 22-24 as a pharmaceutical composition comprising component (i) an effective amount of a non-immunosuppressive pyrrolidine carboxylate or pyrrolidine amide compound having an affinity for FKBP-type immunophilins, component (ii), and component (iii).

II. The 35 U.S.C. § 101 Statutory Double Patenting Rejection A. The Examiner's Position

Beginning on page 4 of Paper No. 5, the examiner rejects claims 25-27 under 35 U.S.C. § 101 as claiming the same invention as that of claims 22-24 of Steiner. The examiner repeats this rejection in Paper No. 9 and states: "Applicants arguments have been considered but are not persuasive. In view of the disclosure in the specification on page 4 it is inherent that the instant compounds are non-immunosuppressive and have an affinity for FKBP-type immunophilins." Paper No. 9, page 2. We agree with the examiner's position in view of our claim interpretation discussed above.

B. The Appellants' Position

Beginning on page 3 of the Brief, appellants argue that the statutory double patenting rejection is improper "when the 'same invention' is <u>not</u> claimed by the two sets of claims".

Appellants discuss reasons why they believe the two sets of claims are not claiming the same invention on pages 3-4 of the Brief.

C. Our Analysis

In determining "same invention" type double patenting, courts ask, for each claim at issue, whether the claim in one patent or application could be literally infringed without literally infringing the claim in the other patent or application. See, e.g., In re Hallman, 655 F.2d 212, 216, 210 USPQ 609, 612 (CCPA 1981); In re Avery, 518 F.2d 1228, 1232, 186 USPO 161, 164 (CCPA 1975); In re Vogel, 422 F.2d 438, 441, 164 USPO 619, 622 (CCPA 1970). The PTO applies a similar test. See M.P.E.P. 804 (citing In re Vogel, 422 F.2d at 440, 164 USPQ at 621). This test can be characterized as a general "infringement test" since an infringement analysis of each of the respective sets of claims is conducted. This "literal infringement" test to determine "same invention" type double patenting may be characterized as a "two-way" test: the claims of the patent are compared to the claims of the other patent or application, and vice versa, to determine whether either set of claims can be literally infringed without literally infringing the other.

According to our claim construction set forth in section I of this decision, a comparison of claim 22 (as rewritten above) with instant claim 25, and vice versa, reveals that claim 22 of Steiner would be literally infringed, as would claim 25 be literally infringed, in

view of their identicalness. As the examiner correctly points out on page 4 of the Answer, appellant's specification (page 4 at lines 20-22) discloses that the instant compound has an affinity for FKBP-type immunophillins and that it does not exert any significant immunosuppressive activity. Hence, we agree with the examiner that the functional aspects of the claims of Steiner are met by the subject matter of the instant claims. Appellants' arguments do not show how the functional aspects would not be met.

Appellants also do not provide convincing arguments showing how one set of claims would be literally infringed, while the other set of claims would not be literally infringed.

III. Conclusion

In view of the above, we therefore affirm the rejection.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR \$ 1.136(a).

AFFIRMED

WILLIAM F. SMITH Administrative Patent Judge))
TONI R. SCHEINER Administrative Patent Judge))BOARD OF PATENT) APPEALS AND) INTERFERENCES)
BEVERLY A. PAWLIKOWSKI))))

BAP/sld

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